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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 16 SEP 2004

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Applicant's or agent's file reference RPS/59585001	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB 03/01123	International filing date (day/month/year) 18.03.2003	Priority date (day/month/year) 18.03.2002
International Patent Classification (IPC) or both national classification and IPC C09K3/12		
Applicant BESPAK PLC		



1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 20.08.2003	Date of completion of this report 19.08.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Wengeler, H Telephone No. +31 70 340-1936 

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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/01123**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-30 as originally filed

Claims, Numbers

1-36 received on 30.05.2004 with letter of 29.05.2004.

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-36
	No: Claims	
Inventive step (IS)	Yes: Claims	1-36
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-36
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/01123

Relevant prior art:

D1: EP-A-0 597 362

D2: EP-A-0 866 096

V

I Novelty (Art. 33(2) PCT)

D1 (claims 1-10) refers to elastomeric polymer compositions and their preparation. The polymer compositions comprise butyl-rubbers and chlorinated butyl rubbers (P. 3, l. 48-58) The curing system comprises a metal oxide, sulphur and sulphur based accelerators (p. 6, l. 29-39) such as e.g dithiocarbamate.

The polymer may be mixed with "conventional compounding ingredients" (p. 6, l. 55-57).

The subject-matter of claims 1, 30 and 31 is distinguished from D1 in that a different sulphur based accelerator is utilized.

D2 (claims 1-12) describes elastomeric compositions comprising isobutylene rubber and a cross linked diene polymer rubber. The composition is utilized as sealing material for medical tools. The cross linking agents useful for the claimed rubber compositions are described on page 5, l. 49- page 6, l. 3). Cross-linking assistants comprise thiazole compounds and dithiocarbamate compounds (p. 6, l. 1-3). The compositions may further contain inorganic fillers (p. 7, l. 47-55), antioxidants, lubricants etc. (p. 8, l. 6-9). The subject-matter of claims 1-37 differs from D2 in that different sulphur based accelerators are utilized.

II Inventive step (Art. 33(3) PCT)

Both prior art documents utilize exclusively tetramethylthiuram disulphide (TMTD) accelerators. The comparative examples of the application are silent about TMTD accelerators. In view of this flaw, the "comparative" examples and the conclusions drawn therefrom must be disregarded.

Hence, in the absence of any convincing evidence that the feature distinguishing the claimed subject-matter from the cited prior art is associated with any technical effect, the objective technical problem to be solved can only be formulated as to provide further compositions having similar quality to those described in D1 and D2.

However, the prior art gives not hint to utilize the specific type of accelerators. The

**INTERNATIONAL PRELIMINARY
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International application No. PCT/GB 03/01123

compositions of claims 1 -36, therefore, are not derivable from any of D1-D2 whether read individually or in any combination. Hence, an inventive step may be acknowledged.

CLAIMS:

1. A seal for a valve for use in a pharmaceutical dispensing device, which seal is formed from an elastomeric composition comprising:

- (a) an isobutylene polymer or co-polymer thereof;
- (b) a cross-linking agent for the isobutylene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and
- (c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

2. A seal as claimed in claim 1, wherein the elastomeric composition comprises one or more of polyisobutylene, polybutene, butyl rubber, halogenated butyl rubber, including derivatives thereof.

3. A seal as claimed in claim 2, wherein the elastomeric composition comprises bromobutyl rubber and/or chlorobutyl rubber, including derivatives thereof.

4. A seal as claimed in any one of the preceding claims, wherein the elastomeric composition comprises a blend of an isobutylene polymer or co-polymer thereof and a chlorine-substituted diene polymer or co-polymer thereof.

5. A seal for a valve for use in a pharmaceutical dispensing device, which seal is formed from an elastomeric composition comprising:

(a) a chlorine-substituted diene polymer or co-polymer thereof;

(b) a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, wherein the cross-
5 linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and

(c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived
10 from a substituted dithiocarbonic acid or derivative thereof.

6. A seal as claimed in claim 5, wherein the elastomeric composition comprises a chlorine-substituted
15 butadiene polymer.

7. A seal as claimed in claim 6, wherein the elastomeric composition comprises 2-chlorobuta-1,3-diene.

20 8. A seal as claimed in any one of the preceding claims, wherein said polysulphide compound is derived from a substituted xanthic acid or derivative thereof.

9. A seal as claimed in any one of the preceding
25 claims, wherein the substituted group in said polysulphide compound is an isopropyl group.

10. A seal as claimed in any one of the preceding
30 claims, wherein said polysulphide compound is diisopropyl xanthogen polysulphide.

11. A seal as claimed in any one of the preceding claims, wherein said polysulphide compound comprises three or more bridging sulphur atoms.

5 12. A seal as claimed in any one of the preceding claims, wherein said polysulphide compound is substantially free from nitrogen, phosphorus and metallic elements.

10 13. A seal as claimed in any one of the preceding claims, wherein the elastomeric composition comprises up to 3 wt.% of the accelerator based on the total weight of the accelerator and polymer in the composition.

15 14. A seal as claimed in claim 13, wherein the elastomeric composition comprises up to 1.5 wt.% of the accelerator based on the total weight of the accelerator and polymer in the composition.

20 15. A seal as claimed in any one of the preceding claims, wherein the weight ratio of the accelerator to the cross-linking agent in the elastomeric composition is in the range of from 1:1 to 3:1.

25 16. A seal as claimed in any one of the preceding claims, wherein the seal further includes a mineral filler.

30 17. A seal as claimed in claim 16, wherein the mineral filler is selected from one or more of magnesium silicate, aluminium silicate, silica, titanium oxide, zinc oxide, calcium carbonate, magnesium oxide magnesium carbonate, magnesium aluminium silicate, aluminium hydroxide, talc, kaolin, clay and amino silane coated clay.

18. A seal as claimed in any one of the preceding claims, wherein the seal further includes a process aid, preferably a low molecular weight polyethylene.

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19. A seal as claimed in any one of the preceding claims, further comprising one or more of a reinforcement agent, a plasticizer, a binder, a stabilizer, a retarder, a bonding agents, an antioxidant, a lubricant, a pigment, a wax, a resin, an antiozonants, a secondary accelerator or an activator.

20. A valve for use in a pharmaceutical dispensing device having a seal as defined in any one of claims 1 to 19.

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21. A pharmaceutical dispensing device having a valve as claimed in claim 20.

22. A pharmaceutical dispensing device as claimed in claim 21 which is a pharmaceutical metered dose aerosol inhaler device.

20

23. A dispensing apparatus for dispensing pressurised fluid comprising a valve body defining a chamber, a valve member extending movably through the chamber and through at least one annular seal co-operating with the valve member and the body to regulate the discharge of fluid, wherein the or at least one of the seals is as defined in any one of claims 1 to 19.

25

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24. A dispensing apparatus which comprises a pressurised dispensing container having a valve body provided with two annular valve seals through which a valve member is axially slidable, said seals being disposed at inlet and outlet apertures of a valve chamber so that the valve functions as a metering valve, wherein at least one of the annular valve seals is as defined in any one of claims 1 to 19.

25. A dispensing apparatus as claimed in claim 23 or claim 24, comprising a pressurised dispensing container operatively connected to the valve body and containing the fluid to be dispensed and a hydrofluorocarbon propellant comprising propellant type 134a or 227.

26. A dispensing apparatus as claimed in any one of claims 23 to 25, wherein the fluid to be dispensed comprises a liquid or particulate product as a solution or suspension in a carrier liquid comprising alcohol.

27. A dispensing apparatus as claimed in claim 26, wherein the alcohol comprises ethanol.

28. A seal as claimed in claim 1, which seal comprises a vulcanisate of an isobutylene polymer or co-polymer thereof, a cross-linking agent for the isobutylene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

29. A seal as claimed in claim 5, which seal comprises a vulcanisate of a chlorine-substituted diene polymer or co-polymer thereof, a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

30. A process for the preparation of a seal for a valve for used in a pharmaceutical dispensing device, the process comprising:

(i) forming a composition comprising a mixture of an isobutylene polymer or co-polymer thereof, a cross-linking agent for the isobutylene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof;

(ii) initiating a cross-linking reaction in the mixture to form a cross-linked elastomeric composition; and

(iii) either before or after (ii) forming the composition into a seal.

31. A process for the preparation of a seal for a valve for use in a pharmaceutical dispensing device, the process comprising:

(i) forming a composition comprising a mixture of a chlorine-substituted diene polymer or co-polymer thereof, a

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cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of
5 peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof;

(ii) initiating a cross-linking reaction in the mixture to form a cross-linked elastomeric composition; and

10 (iii) either before or after (ii) forming the composition into a seal.

32. A process as claimed in claim 30 or claim 31, wherein the step of forming the composition into a seal
15 involves one or more forming techniques selected from compression moulding, injection moulding and extrusion.

33. A process as claimed in any one of claims 30 to 32, wherein the process also involves washing the seals.

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34. A process as claimed in any one of claims 30 to 33, wherein the seals are immersed in an aqueous chlorinated solution.

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35. A process as claimed in claim 34, wherein the aqueous chlorinated solution comprises water and HOCl.

36. A process as claimed in any one of claims 30 to 35, wherein the seals are immersed in a solution comprising
30 water and sodium dichloroisocyanurate (NaDCC).

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